IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Jin Po Lee
Serial No: 10/019,570
Filed: 11-8-2001
For: Multiple Analyte Assay Device
Group Art Unit:1743 Examiner: L.A. Alexander

Hon. Commissioner for Patents
& Trademarks,
Washington, D.C. 20231

Appeal Brief under 37 CFR 1.191

Appellant files this brief in support of its appeal in the subject application:

Real party

The real party in interest is the named inventor, Jin Po Lee.

Related matters

Appellant issued US patent No. 6,514,769 from the same PCT parent application PCT/US98/15,369 as is the case in this application. A terminal disclaimer has been filed and accepted.

Status of the Claims

As set forth in the attached sheets, which separately show the status of all claims and the appealed claims, claims 10 to 17 and 19 were finally rejected and are appealed, claims 1-8 and 18 were finally rejected and are not appealed and claims 8 and 20 to 25 have been withdrawn.

Status of the Amendments,

Typographical errors have been corrected in an amendment following final rejection, which was entered by the examiner.

Summary of Invention.

The present invention provides a biological assay device for simultaneously but separately analyzing for multiple analytes in a fluid sample. The device comprises (page 9, lines 2-12, Figure 1[1]) a generally flat housing base (101) containing a number of parallel slots (102), each separated by a wall or rail allowing (103) different test strips to be placed between the walls in the slots. The test strips (105) contain different binders, antibodies and labels to allow for the visual testing of different analytes (page 9, lines 18-22, Figure 1, 112, 113). The strips extend beyond the housing so as to allow contact of a sample with the strips (page 9, lines 13-22, Figure 2, 102). To protect the integrity of each assay test the housing is equipped with a cover (page 11, lines 5-14, Figure 1, 110,111 115), but containing windows (111) to allow for the viewing of the results in the test and control zones of the analytical assay strip (112, 113) inserted in the housing. In addition the device contains a further removable cover or cap (page 12, lines 2-19 Figure 1, 220, Figures 3A, 3B and 3C), which encloses the protruding ends of the test strips and provides an opening (221) for the fluid sample to be added to a reservoir (222) in the base of the cover housing (223) into which the individual strips are dipped. Thus the device can also be employed without the cover by dipping the exposed assay strips directly into the fluid sample.

The key feature of the claimed invention is that it minimizes any cross contamination of the various assay strips. With the cap on, the exposed strips are protected during transport and any contact between the operator of the test and the sample is further reduced.

Grounds of Rejection to be Reviewed on Appeal

The appealed claims have been rejected as under 35 USC 102 (e) as being clearly anticipated by Kimrov et al US Patent No. 5,976,895 (Kimrov). The

[1] Page numbers, lines and drawing numbers refer to PCT application US98/15369

Examiner argues that Kimrov discloses an assay device comprising a plastic holder that will hold three to five membranes each capable of analyzing for a different drug of abuse. The membranes or assay strips of the reference contain each a detection site and a control site.

Argument

The inventive feature of the multiple analyte assay devices resides in the security the device provides in preventing cross contamination of the different assay strips contained in the housing and any exposure of the operator to the sample. This security is in part due to the walls between the slots containing the different assay strips and the cover, which is in contact with the walls, but also in part due to the secondary cover or cap, which envelops the assay strips protruding from the housing and provides a slot and a sample well for the strips. Thus, although it is possible to use appellant's device without the secondary cover, additional protection against assay cross-contamination is provided if the cover is retained in the analysis. Using the cover with its reservoir and slot prevents excess sample from being absorbed by the strips, which may result in flooding of the assay strip and to misleading results.

Kimrov relates to a multiple analyte assay device involving a particular assay strip construction. Thus the assay strips of Kimrov involve dual membranes placed on top of each other containing different reagents, including labeled reagents (Fig. 1 D, 101 and 106). A sample flowing through the device will be divided, flow through the separate membranes and then be recombined before it reaches the detection and control sites. The housing for the assay strips disclosed allows for several of such strips to be simultaneously exposed to a fluid sample to be analyzed. The strips are completely contained within the housing (Fig. 1 B. 102) and it is through openings in the housing that the fluid sample comes in contact with the assay strip (Fig. 1B, 109). There is no disclosure of any wall separating the assay strips and it is clear that the assay strips do not extend beyond the housing and thus are never exposed directly to the sample.

The appealed claims define a multiple analyte assay device in which the assays trips are in slots in the base of the housing and are separated by walls which prevents cross-contamination between the assay strips. The strips extend beyond the housing. The assay device claimed also comprises a removable cover or cap comprising a top and a base which fits over the extended assay strips. The base of the cover contains a raised portion so as to provide a reservoir for the sample to be analyzed as shown in Figures 3 A, 3 B and 3 C. The sample is added to the device through a sample port in the cover above the reservoir and the strips contact the sample in the reservoir.

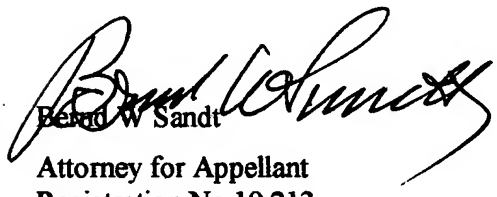
Appellant's claims have been rejected as being anticipated by Kimrov. In order to constitute anticipation the reference must show every element of the claims or an equivalent of each element in a single reference. This is deemed to be hornbook law (See MPEP 2131 and the decisions there cited). Kimrov fails to show slots in a housing for the assay strips with walls between the slots, fails to show strips extending beyond the housing and fails to show a cover for the extended strips, which provides a sample port and reservoir for the sample to be analyzed.

Appellant further points out that the analytical device of the present invention can be employed in two ways. Thus with the cover removed the device can be used by dipping the exposed assay strips into a fluid sample or the device can be employed with the cover in place by adding a fluid sample to be analyzed through the sample port of the cover into the reservoir built into the cover into which the strips extend. Kimrov fails to disclose such a feature or anything equivalent to such.

Conclusion

It is submitted that the reference fails to show all of the elements of the claimed assay device and therefore fails to constitute an anticipation of the claims. A reversal of the final rejection and an allowance of the appealed claims is therefore requested.

Respectfully submitted,



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Certificate under 37 CFR 1.8

I hereby certify that three copies of the foregoing brief being deposited with the United States Postal Service by Priority Mail addressed Mail Stop: Appeal Brief-Patents, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, as of the date set forth below.

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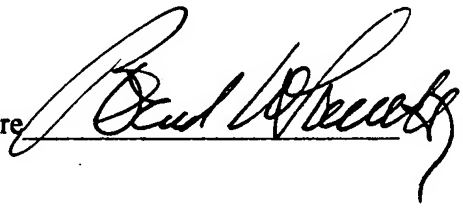
Signature 

Claims on Appeal

10. A device for assaying a fluid for the presence or absence of different analytes comprising:

(A) a base having adjacent slots therein of sufficient length for insertion of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) at least one open end;

(B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific fro a different analyte;

(C) a cover having (a) a first section attached to the upwardmost surface of each raised wall of the slots of the base, wherein the first section of the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed and (b) a second section enclosing the protruding ends of the test strips, the second section comprising:

(i) a sample port formed through which fluid analyte sample may be applied to the protruding ends of the test stripes;

(ii) a floor opposing the sample port, the floor comprising a wall having a raised bar therein which defines a fluid reservoir beneath the sample port.

11. (Original, finally rejected, appealed) The device according to claim 10 wherein the second section of the cover is removable from the first section of the cover.

12. The -device according to Claim 10 further comprising a second transparent

window formed within the cover through which the test strips can be viewed.

13. The device according to Claim 10 further comprising a multiplicity of test strips inserted into each slot of the base, wherein each test strip has a test zone therein and each test zone contains a binder specific for a different analyte.

14. The device according to Claim 13 wherein each binder is specific for a different drug of abuse.

15. (Original finally rejected, appealed) The device according to Claim 13 wherein each test zone is visible through the first transparent window of the cover.

16. The device according claim13 each test strip further comprises a label downstream of the test zone, which label identifies the analyte for which the binder is specific.

17. The device according to claim 12 , wherein the label on the test strip is visible through the second transparent window of the cover.

19. The device according to Claim 13 wherein the drug of abuse is from the group consisting of methamphetamine, opiates/morphine, marihuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylecgonine, methadone, PCP, barbituate, trichloroacetic acid and benzodaizepine.

Status of all Claims

1. (Twice amended, finally rejected, not appealed) A device for assaying a fluid for the presence or absence of different analytes comprising:

(A) a base having adjacent slots therein of sufficient length for insertion of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) at least one open end;

(B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific for a different analyte;

(C) a cover attached to the upwardmost surface of each raised wall of the slots of the base wherein the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed.

2. (Original, finally rejected, not appealed) The device according to Claim 1 further comprising a cap for insertion over the protruding ends of the test strips.

3. (Original finally rejected, not appealed) The device according to Claim 1 further comprising a second transparent window formed within the cover through which the strips can be viewed.

4. (Original finally rejected, not appealed) The device according to Claim 1 wherein each test strip has a test zone therein and each test zone contains a binder specific for a different analyte.

5. (Original finally rejected, not appealed) The device according to Claim 4 wherein each binder is specific for a different drug of abuse.

6. (Original finally rejected, not appealed) The device according to Claim4 wherein each test zone is visible through the first transparent window of the cover.

7. (Original finally rejected, not appealed) The device according to Claim 4 wherein each test strip further comprises a label upstream of the of the test zone, which label identifies the analyte for which the binder is specific.

8 (Twice amended finally rejected, not appealed) The device according to Claim 3, wherein the label on the test strip is visible through the second transparent window.

9. (Withdrawn)

10. (Once previously amended, finally rejected, appealed) A device for assaying a fluid for the presence or absence of different analytes comprising:

(A) a base having adjacent slots therein of sufficient length for insertion of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) at least one open end;

(B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific fro a different analyte;

(C) a cover having (a) a first section attached to the upwardmost surface of each raised wall of the slots of the base, wherein the first section of the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed and (b) a second section enclosing the protruding ends of the test strips, the second section comprising:

(i) a sample port formed through which fluid analyte sample may be applied to the protruding ends of the test stripes;

(ii) a floor opposing the sample port, the floor comprising a wall having a raised

bar therein which defines a fluid reservoir beneath the sample port.

11. (Original, finally rejected, appealed) The device according to claim 10 wherein the second section of the cover is removable from the first section of the cover.

12. (Original, finally rejected, appealed) The device according to Claim 10 further comprising a second transparent window formed within the cover through which the test strips can be viewed.

13. (Original, finally rejected, appealed) The device according to Claim 10 further comprising a multiplicity of test strips inserted into each slot of the base, wherein each test strip has a test zone therein and each test zone contains a binder specific for a different analyte.

14. (Original, finally rejected, appealed) The device according to Claim 13 wherein each binder is specific for a different drug of abuse.

15. (Original finally rejected, appealed) The device according to Claim 13 wherein each test zone is visible through the first transparent window of the cover.

16. (Original, finally rejected, appealed) The device according claim13 each test strip further comprises a label downstream of the test zone, which label identifies the analyte for which the binder is specific.

17. (Twice Amended, finally rejected, appealed) The device according to claim 12 , wherein the label on the test strip is visible through the second transparent window of the cover.

18. (Original, finally rejected, not appealed) The device according to Claim 5 wherein the drug of abuse is from the group consisting of methamphetamine, opiates/morphine, marihuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylecgonine, methadone, PCP, barbituate, trichloroacetic acid and

benzodaizepine.

19. (Original, finally rejected, appealed) The device according to Claim 13 wherein the drug of abuse is from the group consisting of methamphetamine, opiates/morphine, marihuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylecgonine, methadone, PCP, barbituate, trichloroacetic acid and benzodaizepine.

20. (Withdrawn)

21. (Withdrawn)

22. (Withdrawn)

23. (Withdrawn)

24. (Withdrawn)

25. (Withdrawn)